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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/538,531

11/30/2005

Josephus Jan Emeis

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EXAMINER

OGUNBIYI, OLUWATOSIN A

ART UNIT

PAPER NUMBER

1645

MAIL DATE

DELIVERY MODE

11/10/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/538,531	Applicant(s) EMEIS ET AL.	
	Examiner OLUWATOSIN OGUNBIYI	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-6,9,10,12 and 13 is/are pending in the application.
- 4a) Of the above claim(s) 5,10,12 and 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 4, 6 and 9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/6/08 has been entered.

Claims 1, 3-6, 9,10 and 12-13 are pending in the application. Claims 2, 7,8,11 and 14-16 are cancelled.

Claims 1, 3,4, 6 and 9 are under examination.

Rejections Maintained

The rejection of claims 1, 3 and 4 rejected under 35 U.S.C. 102(b) as being clearly anticipated by Zurdo et al. Biochem. J. 1991, Vol. 274, pages 881-884 is maintained for reasons made of record in the office action mailed 6/6/08.

The claims are now drawn to a preparation comprising an isolated membrane fraction of *Rhodospirillum spp.* isolated by sonication and centrifugation, for use as a medicament.

Applicants argue that:

The actual method of making the Zurdo membrane fraction is different than the membrane fraction present in the claimed preparation and as described in the current application. Zurdo et al. prepare intracytoplasmic membranes of *R. rubrum* using a French press to disrupt the cells

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followed by differential centrifugation to produce a fraction of intracytoplasmic membranes, as described in Zurdo et al. on page 1991, right column, at lines 6-9. In contrast, the membrane fraction as recited in the present claims is produced by sonication to disrupt the cells followed by centrifugation. The two preparations are different because they result from different cell homogenization and centrifugation procedures. Therefore, Zurdo et al. does not anticipate the present claims.

Applicants' arguments have been carefully considered but are not found persuasive. The claims are now directed to a product-by-process. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Therefore, the claims are drawn to the preparation comprising isolated membrane fraction of *Rhodospirillum spp* and not the method of making the preparation. Although, Zurdo et al uses a French press to disrupt cells to get to the membrane fraction, the product obtained is still the same i.e. a membrane fraction. There is nothing in the claims to distinguish the structure of the membranes of the instant claims from that of Zurdo et al, both preparations comprise isolated membrane fractions irrespective of how they were obtained.

Claims 1, 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zurdo et al. Biochem. J. 1991, Vol. 274, pages 881-884 in view of ATCC® Bacteria and

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Bacteriophages catalog, 1996 p. 108 (cited previously) and Imhoff et al. International Journal of Systematic Bacteriology (1998) 48:793-798 (cited previously) is maintained for reasons made of record in the office action mailed 6/6/08.

Applicants' arguments regarding the manner of isolation of membrane fractions have been addressed above. Further, Applicants argue that the claimed preparation is inventive because the references only teach that the membrane fraction can be used to study carotenoids and do not mention any use of the preparation as a medicament. Applicants question whether due to preparation and treatment of the membrane fraction as described in Zurdo et al the membrane fraction would still be able to exert this pharmaceutical uses such as for lowering plasma cholesterol.

The recitation of the intended use of the claimed invention i.e. to lower plasma cholesterol must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is the same as that of the instant claims i.e. a preparation comprising an isolated membrane fraction of *Rhodospirillum spp* and/or *Phaeospirillum spp* and absent any other structural distinction between the membrane fraction of the prior art and that of the claims, the product of the prior art is capable of performing the intended use or properties of the claimed product. Further, the instant claims are drawn to the claimed product and not drawn to the uses of the claimed product for the preparation of a medicament.

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The rejection of claims 1, 6 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zurdo et al. Biochem. J. 1991, Vol. 274, pages 881-884 and ATCC® Bacteria and Bacteriophages catalog, 1996 p. 108 (cited previously) and Imhoff et al. International Journal of Systematic Bacteriology (1998, cited previously) 48:793-798 as applied to claims 1, 3 and 4 above further in view of Schmidt-Dannert et al. Current Opinion in Biotechnology, 2000, Vol. 11, pages 255-261 and Wang et al, CN 11172653 02/11/1998 (cited previous action) is maintained for reasons made of record in the office action mailed 6/6/08.

Applicants' arguments regarding the preparation of membrane fraction has been addressed above. Further, Applicants argue that in applying Wang, which allegedly teaches the use of *Rhodospirillum spp.* as a food additive, the Office Action states that the *Rhodospirillum spp.* of Wang et al inherently comprises a membrane fraction. Applicants argue that a disclosure of the use of whole cells in a food additive or supplement does not signify that administering only an isolated component of such cells would have the same effect as the whole cell preparation and one cannot predict from Wang et al whether any of the components removed during the membrane isolation process are relevant to the use as a food additive.

Applicants' arguments have been carefully considered but are not persuasive. It was pointed out in the rejection that since the beneficial carotenoids are present in the membranes of said *Rhodospirillum spp* it would have been prima facie obvious to one of ordinary skill in the art to use the isolated membranes of Zurdo et al and ATCC® Bacteria and Bacteriophages catalog and Imhoff et al as combined in the food supplement or food/feed instead of the whole bacterium. Wang was cited for the general teaching that *Rhodospirillum species* is used as food additive or supplement to food but because Schmidt-Dannert et al teaches that carotenoids are

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used as food colorants in animal feed it would be obvious to add isolated membranes which contain carotenoids to food instead of the whole bacterial cell. The membrane fractions contained carotenoids (see Zurdo et al p. 882 column 2 first full paragraph) thus there should not be any concern that the carotenoids are removed from the membranes during the isolation of the membrane fraction. Also, food grade bacterial membrane fractions are well known in the art (See Fung et al Journal of Rapid Methods and Automation in Microbiology 5 (1997). Thus, there would be a reasonable expectation of success in adding the membrane fractions of *Rhodospirillum* and/or *Phaeospirillum* spp to a food.

Status of Claims

Claims 1, 3, 4, 6 and 9 are rejected. No claims allowed.

Prior Art Made of Record Pertinent to Applicants Disclosure:

US 6,916,478 B2 (KADURUGAMUWA ET AL) July 12, 2005 filed Sept 6, 2002 – discloses vaccines and pharmaceutical compositions using membrane vesicles of microorganisms.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to OLUWATOSIN OGUNBIYI whose telephone number is 571-272-9939. The examiner can normally be reached on M-F 8:30 am- 5 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Oluwatosin Ogunbiyi/
Examiner, Art Unit 1645

/Patricia A. Duffy/
Primary Examiner, Art Unit 1645